

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE: NATIONAL PRESCRIPTION</b>	)	<b>MDL 2804</b>
<b>OPIATE LITIGATION</b>	)	<b>Case No. 1:17-md-2804</b>
	)	<b>Judge Dan Aaron Polster</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
<i>Track One Cases</i>	)	<b><u>OPINION AND ORDER GRANTING</u></b>
	)	<b><u>DEFENDANTS' MOTION TO</u></b>
	)	<b><u>EXCLUDE WHITELAW</u></b>
	)	

Before the Court is Defendants'<sup>1</sup> Motion to Strike the Opinions of Seth B. Whitelaw ("Whitelaw Motion") (**Doc. #: 1918**). The Court has carefully considered the Whitelaw Motion, Plaintiffs' Response (**Doc. #: 2114**), and Defendants' Reply (**Doc. #: 2517**) and **GRANTS** the Whitelaw Motion.

**I. Legal Standards.**

The Court incorporates the general legal standards set forth in the Court's Opinion and Order regarding Defendants' motion to exclude the opinion and testimony of Prof. Meredith Rosenthal. *See* Doc. #: 2495.

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<sup>1</sup> "Defendants," as used by Whitelaw and in this Order, are McKesson Corporation, AmerisourceBergen Drug Corporation, CVS Rx Services, Inc., CVS Indiana, L.L.C. (collectively "CVS"), Walgreen Co., Walgreen Eastern Co. (collectively "Walgreens"), Mallinckrodt plc, Mallinckrodt, LLC, and SpecGx LLC (collectively "Mallinckrodt"). *See* Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Seth Whitelaw's Opinions and Proposed Testimony ("Pls. Opp. Resp. re Whitelaw") at 1, n. 1 (Doc. #: 2114).

## II. Introduction.

Plaintiffs designated Whitelaw as an expert on: (1) the relevant standards applicable to the design, implementation, and operation of corporate and controlled substance compliance programs for pharmaceutical manufacturers and distributors; (2) application of these standards to controlled substance manufacturers and distributors; and (3) the effectiveness of Defendants' opioid product compliance programs from 1996 until 2018. *See* Whitelaw Report at 2 (Doc. #: 1999-25).<sup>2</sup> According to Plaintiffs, "Whitelaw offers opinions concerning the proper elements of a compliance program for a reasonable pharmaceutical manufacturer and distributor and offers an assessment of Defendants' compliance programs based upon those elements." Pls. Opp. Resp. re Whitelaw at 13 (Doc. #: 2114).

Whitelaw is a lawyer with experience in corporate compliance, including pharmaceutical industry compliance. Defendants seek to exclude Whitelaw's opinions, arguing: (1) he lacks the qualifications to serve as a suspicious order monitoring system ("SOMS") program expert; (2) his model SOMS program is unreliable because it was created solely for this litigation and employs a methodology that draws heavily from the Federal Sentencing Guidelines ("FSG"), which are not used by either the DEA or industry participants for this purpose; and (3) he invades the province of the jury by opining on an ultimate issue. Each of these arguments will be addressed below. First, however, the Court provides an overview of Whitelaw's opinions and analysis.

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<sup>2</sup> Whitelaw's Report is an exhibit to the Memorandum of Points and Authorities in Support of Defendants' Daubert Motion to Exclude the Opinions of Seth B. Whitelaw ("Def. Mot. to Excl. Whitelaw") (Doc. #: 1918-5). However, the report accompanying the motion is missing pages 45-278. *See id.* Accordingly, the Court cites to the report filed as an exhibit to the Notice of Corrected Filing of Expert Reports. *See* Notice, Ex. 25 (Doc. #: 1999-25).

### **III. Whitelaw's Opinions.**

#### **A. Overview of Whitelaw's methodology.**

Whitelaw's opinions and analysis have, at their core, a SOMS program he developed for purposes of this litigation. Whitelaw characterizes his SOMS program as "what good looks like." Whitelaw Report at 23-42 (Doc. #: 1999-25). Whitelaw then assesses whether the SOMS programs of each Defendant meet the criteria of his program, and then measures each Defendant's performance by a compliance maturity and program effectiveness model. *See, e.g., id.* at 43-48. Whitelaw assesses whether each company "worked to establish a suspicious order monitoring system, as well as controlled substances and corporate compliance systems;" and, if so, whether the company "met its three-prong program effectiveness requirement by (a) having a program that prevents and detects criminal conduct by an organization's employees and (b) maintaining effective controls against diversion, including (c) maintaining and operating an effective system to identify, hold, investigate and report suspicious orders of controlled substances." *Id.* at 43-44.

#### **B. Standards reviewed by Whitelaw.**

Whitelaw summarizes an assortment of sources he considers relevant to controlled substance compliance. Some relate to SOMS and controlled substances. Some do not. *See* Whitelaw Report at 4, 23 (Doc. #: 1999-25). Whitelaw first provides a narrative summarizing what he contends are general corporate compliance standards, including the standards found in the FSG. The FSG apply when an organization is convicted of a felony or class A misdemeanor. *See* U.S. Sentencing Commission, Guidelines Manual (Nov. 1991) at Introductory Comments and § 8A 1.1) (Doc. #: 1918-8). They are neither part of the CSA nor part of DEA regulations applicable to the CSA. They are "not pharmaceutical-specific but rather, apply to corporations across all industries." Whitelaw Report at 93 (Doc. #: 1999-25).

Several FSG provisions refer to the need for organizations to have an “effective program” to prevent and detect violations of law. *See, e.g.*, U.S. Sentencing Commission, Guidelines Manual (Nov. 1991) at § 8C2.5 (f). (Doc. #: 1918-8). Having an “effective program” can result in a lesser punishment. *See id.* The FSG definition of an “effective program to prevent and detect violations of law” sets forth seven steps which an organization must demonstrate to establish the requisite due diligence in detecting and preventing criminal conduct to qualify for a sentence reduction. *See id.* at § 8A 1.2 Comment 3(k). The most recent revisions to the FSG add an eighth step, expanding their scope beyond detecting and preventing criminal conduct to promoting “an organizational culture that encourages ethical conduct and a commitment to compliance with the law.”<sup>3</sup> Whitelaw Report at 10 (Doc. #: 1999-25) (quoting U.S. Sentencing Commission, Guidelines Manual (Nov. 2004) at § 8B 2.1); *see also* Whitelaw Report at 27. *See id.*

To support his reliance on the FSG, Whitelaw refers to standards generated by the Office of Inspector General (“OIG”) for Health and Human Services. These standards are directed only to pharmaceutical manufacturers; however, Whitelaw believes they should also apply to distributors. *See* Whitelaw Report at 11-12 (Doc. #: 1999-25). The OIG standards are not specific to the CSA, SOMS programs, or controlled substances. *See* Def. Mot. to Excl. Whitelaw at 11

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<sup>3</sup> The eight FSG steps are summarized as: (1) creating compliance standards and procedures reasonably capable of reducing the prospect of criminal conduct by employees and agents; (2) assigning high level personnel to oversee compliance with these standards and procedures; (3) ensuring individuals the organization knew or should have known have a propensity to engage in illegal conduct do not have substantial discretionary authority; (4) effectively communicating the standards and procedures to employees and agents through training and publication dissemination; (5) creating monitoring programs, audits, and a reporting system to achieve compliance with standards; (6) consistently enforcing standards by appropriate case-specific disciplinary mechanisms; (7) responding appropriately to offenses to prevent similar activity from occurring; and (8) periodic assessment of the risk of criminal conduct and the action necessary to address it based, *inter alia*, on industry practice called for by applicable government regulations. *See* Whitelaw Report at 8-10 (Doc. #: 1999-25).

(Doc. #: 1918-1). Whitelaw also references standards in the Affordable Care Act,<sup>4</sup> and general guidance from the DOJ and OIG on compliance program effectiveness.<sup>5</sup> *See* Whitelaw Report at 7-13 (Doc. #: 1999-25). These provisions are also not CSA- or DEA-specific.

Whitelaw next transitions to a pharmaceutical-centered analysis, summarizing the CSA and DEA regulations, as well as DEA guidance on controlled substances from the Controlled Substances Security Manual & Suspicious Order Task Force, the Chemical Handler's Manual, the DEA Industry Initiative, DEA letters to registrants, and *Master's Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). Whitelaw also discusses industry guidance. *See id.* at 13-22.

**C. Whitelaw's SOMS program and his Compliance Maturity and Program Effectiveness Model.**

After analyzing these applicable standards, Whitelaw describes his own SOMS program, which is based on the FSG and his interpretation of the eight steps described above. Whitelaw distills the eight FSG steps to eight elements<sup>6</sup> and then boils these elements down to three general categories: (a) Company Commitment; (b) Program Core; and (c) Accountability. Whitelaw

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<sup>4</sup> In Whitelaw's opinion, the Affordable Care Act requires corporate compliance programs to contain certain "core elements" for participation in, and reimbursement from, federal health care programs like Medicare, Medicaid, and Children's Health Insurance Program. *See* Whitelaw Report at 6 (Doc. #: 1999-25). These "core" elements have not yet been identified; however, Whitelaw considers the standards referenced in his report indicative of what these "core elements" are likely to be. *See id.* at 13, n. 31.

<sup>5</sup> In 2017, the DOJ and the OIG identified standards for corporate compliance effectiveness. These standards were not a mandatory checklist, but were to be considered by organizations when making individualized determinations about their compliance programs. *Id.* at 13. They are not directed specifically to controlled substances or SOMS programs.

<sup>6</sup> These eight elements are: (1) Organization and Resources; (2) Due Diligence; (3) Written Standards; (4) Training and Compliance; (5) Monitoring, Auditing, and Investigation; (6) Corrective Actions; (7) Enforcement (i.e. Discipline or other consequences for violating the standards); and (8) Periodic Risk Assessment. *See* Whitelaw Report at 24 (Doc. #: 1999-25).

Report at 24 (Doc. #: 1999-25). For each prong of his compliance program, Whitelaw discusses the “attributes” he would “expect to see” in a reasonable program. *See, e.g., id.* at 28, 30, 34, 36, 38 (Doc. #: 1999-25). Although he applies his program to each Defendant, Whitelaw acknowledges the FSG rely on each organization to determine “[t]he precise actions necessary for an effective program to prevent and detect violations of law” and that there are a “number of factors” that go into this decision. Whitelaw Report at 9 (Doc. #: 1999-25) (quoting U.S. Sentencing Commission, Guidelines Manual, § 8A.1.2, comment (n. 3k) (Nov. 1991)).

Whitelaw next describes his Compliance Maturity and Program Effectiveness Model for measuring compliance with his program. In Whitelaw’s words: “After defining ‘what good looks like’ the next step is to measure it.” Whitelaw Report at 43 (Doc. #: 1999-25). Whitelaw’s model is premised on a general maturity model;<sup>7</sup> into which he incorporates certain elements of his compliance program. *See* Whitelaw Report at 43-44 (Doc. #: 1999-25). The majority of Whitelaw’s report is devoted to his analysis of Defendants’ documents and activities and his interpretation of whether each Defendant complied with the elements of his own SOMS program and whether they rank on his model. *See id.* at 48-278. Whitelaw’s general opinions include observations that one or more Defendants:

failed to make necessary changes to achieve a robust and effective compliance function in accordance with the values, principles and societal expectations for those involved in distributing prescription opioids;

studiously avoided having to address customer behaviors known, or which should have been known, to be inappropriate and likely diversionary;

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<sup>7</sup> In general terms, a maturity model is used to determine the effectiveness of an organization and can be used to assess capabilities necessary to improve performance. Maturity models are structured by levels of effectiveness and identify stages through which organizations progress as they define, implement, and improve their processes. For example, Whitelaw’s model has four levels: (a) Fundamental; (b) Maturing; (c) Advancing; and (d) Leading. *See id.* at 43.

failed to act responsibly to undertake reasoned, prudent and careful measures expected of those handling prescription opioid products, even while acknowledging the exponential increase in opioid usage;

failed to manifest good corporate responsibility by not undertaking the reasoned, prudent and careful measures expected of those manufacturing and selling opioid products;

failed to make the necessary changes to anti-diversion practices to achieve a robust and effective compliance function in accordance with the values, principles and societal expectations for those involved in distributing prescription opioids;

treated as an afterthought, if it was recognized at all, the need for distribution centers to maintain reasoned, prudent and careful measures to prevent opioid diversion (*e.g.*, a SOMS program) expected of those handling prescription opioid medicines;

failed to make controlled substances efforts part of overall corporate compliance programs in a meaningful way;

determined to only do the bare minimum, as expressed by the DEA, which resulted in token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market, let alone to fulfill required legal and regulatory obligations;

designed, implemented, and operated SOMS programs to avoid classifying customer orders as “suspicious” and to avoid having to stop suspect opioid shipments to customers; and

exhibited indifference to any negative societal impact flowing from their actions.

*See* Whitelaw Report at 45-46 (Doc. #: 1999-25).

#### **IV. Should Whitelaw’s Testimony be Excluded?**

##### **A. Is Whitelaw Qualified to Offer his Opinions?**

Whitelaw received his law degree from Washington & Lee University School of Law in 1988 and an LL.M in administrative law from George Washington School of Law in 1989. In 2011, he was awarded an S.J.D. in Health Law from Widener University School of Law. Since graduation, Whitelaw’s career has focused on corporate compliance, with a particular emphasis on FDA compliance. *See* Whitelaw Report at 1, 279-282 (Doc. #: 1999-25). He has designed, built,

and run a total of four compliance programs for two medical device companies and two pharmaceutical companies. *Id.* In addition, Whitelaw teaches monitoring and auditing in the Healthcare Compliance Certificate program at Mitchell Hamline School of Law. *Id.*

Prior to being retained by Plaintiffs, Whitelaw had neither general experience with controlled substance compliance programs nor particular experience with SOMS compliance programs. He also had no compliance experience involving opioids, controlled substances, the Controlled Substances Act, or DEA regulatory programs pertaining to the manufacture and distribution of controlled substances. Neither the pharmaceutical company nor the medical device company for which he worked manufactured or distributed opioids and he had never designed, operated, or audited a controlled substance compliance program. *See* Def. Mot. to Excl. Whitelaw at 1-2, 5-8 (Doc. #: 1918-1). On one occasion, as a consultant, Whitelaw was part of team asked to propose enhancements to a controlled substance anti-diversion program. *See* Pls. Opp. Resp. re Whitelaw at 4 (Doc. #: 2114). His team, however, was not hired. *See* Defendants' Reply in Support of Defendants' *Daubert* Motion to Exclude the Opinions of Seth B. Whitelaw ("Def. Reply re Whitelaw") at 3 (Doc. #: 2517).

To educate himself to render opinions in this case, Whitelaw reviewed a plethora of statutes, documents relating to Defendants and their policies and procedures, shipping data, and other material produced in discovery and publicly available. *See* Whitelaw Report at 3-4, 259-278 (Doc. #: 1999-25); He also conferred with Plaintiffs' counsel and Plaintiffs' expert, James Rafalski, a retired DEA diversion investigator, *see* Whitelaw Report at 3-4 (Doc. #: 1999-25); May 17, 2019 Deposition of Dr. Seth B. Whitelaw ("Whitelaw Depo. II") at 829:5-14 (Doc. #: 1918-7), but did not meet with any current employees of the DEA. *See* May 16, 2019 Deposition of Dr.

Seth B. Whitelaw (“Whitelaw Depo. I”) at 36:13-24 (Doc. #: 1918-7). Prior to his work for Plaintiffs, Whitelaw did not consider himself to be an expert on SOMS monitoring:

- Q. Okay. Prior to this litigation, have you ever held yourself out to a potential client as a suspicious order monitoring expert?
- A. Other than the work that I did on a proposal for Deloitte, which, again, was more of a compliance process assessment for suspicious order monitoring program, I don’t recall ever putting that moniker on my name.

See Whitelaw Depo. II at 829:5-14 (Doc. #: 1918-7).

Defendants argue Whitelaw is unqualified to offer his opinions because he lacks specific experience in controlled substance compliance, SOMS programs, the CSA, and the DEA. See Def. Mot. to Excl. Whitelaw at 5-8 (Doc. #: 1918-1). In response, Plaintiffs contend Whitelaw’s general compliance background is sufficient to qualify him as a SOMS program and controlled substance handling expert. Plaintiffs emphasize that Whitelaw did more than simply assess Defendants’ SOMS programs; instead, they claim, he “undertook a comprehensive examination of Defendants’ compliance programs as a whole, which included their suspicious order monitoring efforts ....” Pls. Opp. Resp. re Whitelaw at 3. (Doc. #: 2114). Plaintiffs point to Whitelaw’s experience with sample accountability programs involving the Prescription Drug Marketing Act, also noting that, even though his firm was not hired, his participation on the team asked to propose enhancements to a controlled substance anti-diversion program establishes his expertise. *Id.* at 4. Finally, Plaintiffs assert Whitelaw’s experience was supplemented by his conversation with Plaintiffs’ expert, Rafalski. *Id.*

The Court finds Plaintiffs’ arguments unpersuasive. First, as Defendants’ point out, Whitelaw’s report focuses on Defendants’ *controlled substance* compliance efforts, not on compliance efforts in other areas. Whitelaw describes his opinions to include the standards applicable to the design, implementation, and operation of controlled substance compliance

programs for pharmaceutical manufacturers and distributors, application of these standards; and effectiveness of Defendants' opioid product compliance programs between 1996 and 2018. *See* Whitelaw Report at 2 (Doc. #: 1999-25). He offers sweeping opinions about Defendants, their SOMS programs, how they handled controlled substances, and whether they met their compliance obligations. As Defendants' note, most of his nearly 300-page report provide "Individual Company Reviews" focused on the Defendants' SOMS and controlled substance activities. *See* Def. Reply re Whitelaw at 1, 3 (Doc. #: 2517). Quite simply, Whitelaw's report and opinion focus almost exclusively on Defendants' SOMS programs, an area in which he had no experience prior to this litigation.

The Court rejects Plaintiffs' argument that Whitelaw's involvement with the Prescription Drug Marketing Act makes him a SOMS program or controlled substance handling expert, inasmuch as Whitelaw acknowledged that none of this work involved controlled substances. *See, e.g.,* Whitelaw Depo. I at 74:1-77:6; *see also* Def. Reply re Whitelaw at 4 (Doc. #: 2517). Similarly, Whitelaw's tangential involvement on a team tasked with proposing enhancements to a controlled substance anti-diversion program does not imbue him with expertise on SOMS programs and DEA compliance matters. Whitelaw's team of at least six people was not hired for this assignment and the level of Whitelaw's involvement is unclear. *See* Def. Reply re Whitelaw at 3 (Doc. #: 2517). Any proposals he advanced are untested in the real world. And, Whitelaw's reliance on his discussion with Plaintiffs' expert, Rafalski, emphasizes Whitelaw's lack of experience in connection with SOMS programs and DEA involvement with these programs.<sup>8</sup>

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<sup>8</sup> Federal Rule of Evidence 703 allows an expert to rely on hearsay, including the opinions of other experts; however, this reliance cannot be used to enhance the witness's fundamental expertise. Whitelaw has no SOMS or controlled substance experience, and he does not become qualified to offer opinions on these subjects merely because he spoke to one of Plaintiffs' experts.

On this record, the Court finds Whitelaw lacks “sufficient specialized knowledge to assist the jurors in deciding the particular issues in this case.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999). Although Whitelaw has substantial general compliance experience, the Court concludes he does not have sufficient specific experience with the design, implementation, and operation of SOMS programs or DEA requirements to qualify him as an expert pursuant to Rule 702, which requires an expert have “specialized knowledge” regarding the areas about which he will testify. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528 (6th Cir. 2007) (quoting Fed. R .Evid. 702).

The qualifications component of Rule 702 has always been treated liberally; however, this does not mean a witness qualifies as an expert in a particular area simply because he claims he is one. *See Pride v. BIC Corporation*, 218 F.3d 566, 577 (6th Cir.2000); *Newell Rubbermaid, Inc. v. Raymond Corp.*, No. 5:08CV2632, 2010 WL 2643417, \*3 (N.D. Ohio July 1, 2010). “In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue.” *Lawrence v. Raymond Corp.*, No. 3:09 CV 1067, 2011 WL 348324, \* 4 (N.D. Ohio Aug. 4, 2011) (citing *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir.1997); *Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 382 (5th Cir.1996)). Whitelaw’s lack of experience with SOMS exceeds a lack of familiarity with “pertinent statutory definitions or standards,” which simply impact his credibility. *Davis v. Combustion Engineering Inc.* 742 F.2d 916, 919 (6th Cir. 1984). Instead, his lack of

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*See In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 816 F.Supp.2d 442, 450 (W.D. Ky. 2011) (barring expert from opining about warning labels where he merely spoke to another expert about the labels, to make up for his own lack of expertise); *see also In re Welding Fume Prod. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699546, at \*35 (N.D. Ohio June 4, 2010).

relevant experience goes to the heart of his opinions and analysis, thereby, making them inadmissible.

**B. Are Whitelaw's SOMS program and model reliable?**

Even if Whitelaw was qualified to offer his opinions, the Court would exclude them because they are unreliable.

It is Defendants' position that the FSG do not form a reliable foundation for Whitelaw's opinions because they apply to criminal sentencing and not to evaluating DEA controlled substance monitoring programs or the design and evaluation of SOMS programs. *See* Def. Mot. to Excl. Whitelaw at 9-10 (Doc. #: 1918-1). Plaintiffs defend the validity of the FSG and submit evidence supporting Whitelaw's position that the FSG are utilized by various organizations (including some of the Defendants) in conjunction with general compliance programs. *See, e.g.,* Pls. Opp. Resp. re Whitelaw at 6-11 (Doc. #: 2114). However, there is no evidence that any organization has ever used the FSG in conjunction with a SOMS program. Neither is there any evidence that the FSG is used by the DEA to assess the propriety of any SOMS program. In fact, the unrefuted evidence is to the contrary. The DEA's Section Chief of the Pharmaceutical Investigations Section of the Office of Diversion Control testified that the DEA does *not* use the FSG to evaluate SOMS programs and does not train its investigators to rely on the FSG to evaluate SOMS programs:

Q. The DEA doesn't use the federal sentencing guidelines to evaluate registrants' suspicious order monitoring programs, correct? ...

THE WITNESS. Yes. Correct.

Q. Correct that they do not?

A. Do not.

Q. Thank you sir.

Now, when you were training division investigators, did you ever instruct diversion investigators to rely on the federal sentencing guidelines to evaluate registrants' suspicious order monitoring programs? ...

THE WITNESS. No.

May 17, 2019 Deposition of Thomas Prevoznik at 1202:2-20 (Doc. #: 1918-12). *See also* Def. Mot. to Excl. Whitelaw at 10 (Doc. #: 1918-5). Even Whitelaw acknowledges he has never used his model to evaluate a SOMS program until this litigation. *See* Whitelaw Depo. II at 715:8-19 (Doc. #: 1918-7). Nor has anyone ever used his model to measure a distributor's compliance with the CSA.

Q. Dr. Whitelaw, are you aware of anyone who has ever used a scale such as the one that you prepared in Figure 2 to measure how a distributor complies with the Controlled Substances Act and its associated regulations?

A. Not in that context, no.

Q. Now looking at – looking at your model in Figure 2, is there a point system or some other system that you apply to evaluate the maturity of the compliance program?

A. There is not a strict quantitative methodology. It is more a qualitative assessment.

Whitelaw Depo I at 245:12-18 (Doc. #: 1918-7).

An expert's methodology must be reliable. *See* Fed. R. Evid. 702. Testimony can be reliable only if it is “based on sufficient facts or data” or “the product of reliable principles and methods” which the expert, in turn, has applied to the facts of the case. Fed. R. Evid. 702. The requirement that expert testimony be evaluated to determine its “reliability” stems from *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993), where the Supreme Court tasked trial courts to conduct a “preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93 (citations omitted). *Daubert's* analysis

was extended to non-scientific expert testimony by *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

Here, Plaintiffs would have Whitelaw's new and original compliance program, created solely for this case, serve as the benchmark for Defendants' conduct. Whitelaw's methodologies are untested in the realm of controlled substance monitoring and DEA compliance assessment. There has been no evidence submitted concerning whether Whitelaw considered other compliance measures—either currently in use or potentially available—and, if so, why he did not use them. Further, Whitelaw submits his own interpretation, and application of the FSG. As a result, even if there were other contexts in which the FSG were used, there is no indication that the “version” of the FGS used in those contexts was the same as the version proposed by Whitelaw. Plaintiffs rely on Whitelaw's *ipsi dixit* that his program (and model) are appropriate, even though he has no experience with SOMS programs and his methodologies have never been used for the purposes advanced here. *See Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 254 (6th Cir. 2001); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). The Court finds that Whitelaw's opinions are premised on methodology that does not meet *Daubert's* non-exhaustive list of factors, including that Whitelaw's methodology has not been tested and is not generally accepted in the relevant community. *See Daubert*, 509 U.S. at 582-594.

Moreover, not only does Whitelaw acknowledge he devised his methodology for purposes of this case, there is also evidence that Whitelaw's opinions are, at least in part, at odds with positions he adopted before being retained as an expert by Plaintiffs. *See* Def. Mot. to Excl. Whitelaw at 11-2 (Doc. #: 1918-1). This additional “prepared solely for litigation” factor raises a red-flag highlighting that Whitelaw's opinions may not be reliable. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 431 (6th Cir. 2007); *Newell Rubbermaid, Inc. v. Raymond Corp.*,

676 F.3d 521, 527 (6th Cir. 2012). The Sixth Circuit “has recognized for some time that expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert’s line of scientific research or technical work, should be viewed with some caution.” *Manitowoc Boom Trucks.*, 484 F.3d at 434; *see also Mike’s Train House, Inc v. Lionel, L.L.C.*, 472 F.3d 398, 408 (6th Cir. 2006) (“We have been suspicious of methodologies created for the purpose of litigation.”). While the “prepared solely for litigation” factor may not be enough by itself to support a finding of unreliability, when combined with the other evidence and arguments presented by Defendants, it is convincing.

In addition to the arguments advanced by Defendants, the Court notes the subjectivity of many of Whitelaw’s opinions, which address Defendants’ motives, state of mind, and intentions. This testimony is not as much an “expert” opinion as it is a personal opinion about Defendants’ behavior: “[T]estimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury” and is inadmissible. *Indiana Ins. Co. v. General Elec. Co.*, 326 F.Supp.2d 844, 847 (N.D. Ohio 2004) (citing *McGowan v. Cooper Indus., Inc.*, 863 F.2d 1266, 1273 (6th Cir.1987)); *see also Rheinfrank v. Abbott Labs., Inc.*, 2015 WL 13033172, \*9 (S.D. Ohio Oct. 2, 2015), *aff’d* 680 F. App’x 369 (6th Cir.. 2017) (expert prohibited from testifying as to the “knowledge, motivations, state of mind, or purposes” of defendants and others). Whether expressed as opinion or as a summary of documents, Whitelaw may not render these types of opinions. *See Fletcher v. VanDyne*, No. 2:07-cv-325, 2009 WL 3789925, at \*3 (S.D. Ohio Feb. 24, 2009) (“the Court will not permit the expert to speculate as to the defendants’ states of mind”). This type of testimony is not only unhelpful to the jury but also is unduly prejudicial. *See Fed. R.*

Evid. 403 (relevant evidence can be excluded if the probative value is outweighed by the danger that it will mislead the jury).<sup>9</sup>

In sum, Plaintiffs have not met their burden to establish that Whitelaw's methodology would be reliable as applied to the facts of this case.

### **C. Does Whitelaw improperly opine on ultimate issues?**

Defendants also complain that Whitelaw offers opinions on the "ultimate issue" of whether Defendants' SOMS programs complied with the CSA and its corresponding DEA regulations. *See* Def. Mot. to Excl. Whitelaw at 13 (Doc. #: 1918-1). Plaintiffs respond that Whitelaw's opinions are directed only to the elements of a compliance program for a reasonable pharmaceutical manufacturer and distributor, and that he simply offers an assessment of Defendants' compliance program based upon those elements, which is not a legal conclusion requiring exclusion. *See* Pls. Opp. Resp. re Whitelaw at 13 (Doc. #: 2114).

Plaintiffs are correct that, under Federal Rule of Evidence 704(a), an expert opinion is not inherently objectionable simply because it "embraces an ultimate issue to be decided by the trier of fact." However, Rule 704(a) "does not lower the bar so as to admit all opinions." *United States v. Smith*, 70 Fed.App'x 804, 809 (6th Cir. July 15, 2003), *cert. denied*, 540 U.S. 976 (2003) (citing *Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985)). An evidentiary problem remains

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<sup>9</sup> In addition to Defendants' arguments, the Court also notes that substantial portions of Whitelaw's narrative summary of documents and events constitutes an impermissible factual narrative. *Rheinfrank*, 2015 WL 13033172, \*9 (an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 542-545 (S.D.N.Y. 2004) (an expert narrative is inadmissible when it is a repetition of the factual allegations in plaintiffs' complaint, involving nothing technical or scientific, because the expert is providing only simple inferences drawn from uncomplicated facts). Even absent the Court's other grounds for exclusion, this also weighs against allowing certain portions of Whitelaw's testimony.

if “testimony containing a legal conclusion is allowed, as it may convey a witness’s unexpressed, and perhaps erroneous, legal standards to the jury.” *Id.*

Defendants rightly point out that certain statements in Whitelaw’s report amount to legal opinions. *See* Def. Reply re Whitelaw at 7 (Doc. #: 2517). Plaintiffs are correct that not *all* of Whitelaw’s opinions fall into this category, but the Court must also exclude those portions of Whitelaw’s testimony that offer legal conclusions. Given the voluminous nature of Whitelaw’s report and the rulings stated above, the Court need not identify each legal conclusion which would be excluded.

In sum, for all the reasons described above, Defendants’ Motion to Exclude Seth B. Whitelaw’s Opinions and Proposed Testimony (Doc. #: 1918) is **GRANTED**.

**IT IS SO ORDERED.**

/s/Dan Aaron Polster August 29, 2019  
**DAN AARON POLSTER**  
**UNITED STATES DISTRICT JUDGE**